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Carsten Schelp

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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

05/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/024,258

Applicant(s)

SCHELP ET AL.

Examiner

GARY W. COUNTS

Art Unit

1641

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/04/09 has been entered.

### **Status of the claims**

2. Currently, claims 1-31 are pending. Claims 23-31 are withdrawn as being directed to a non-elected invention. Claims 1-22 are under examination.

### **Withdrawn Rejections**

3. All rejections of claims not reiterated herein, have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 the recitation "using measurement method 2, wherein measurement method 1 and measurement method 2 are different" is indefinite and confusing. There is no antecedent basis for measurement method 1 or for measurement method 2. Further, it is unclear what measurement methods applicant is referring to. Thus, it is unclear what applicant is trying to encompass. Applicant is also reminded that the claims must stand on their own merits and that limitations from the specification are not read into the claim.

Claim 2 the recitations "the method of claim 1" and "wherein the method comprises" is vague and indefinite because it is unclear if applicant is referring to measurement method 1, measurement method 2 or the method as recited in the preamble of claim 1. Claim 1 as currently recited appears to recite three methods. See also deficiencies found in the remaining dependent claims.

Claim 5 is confusing and unclear because it is unclear if the steps (i) - (iii) recited in claim 5 replace steps (i) -(ii) recited in claim 1 or if claim 1 further comprises the steps listed in claim 5. Further, if the steps recited in claim 5 replace those recited in claim 1 it is unclear in what way they would replace the steps of claim 1.

Claim 5 is vague and indefinite in reciting "R3 which is associated with a member X of a specific binding pair". It is unclear if the R3 associated with L2 recited in claim 1 further comprises a member X or if the R3 or the L2 is considered to be a member X. or if the analyte is a member X because it is a member of a specific binding pair when bound to R3. The claim does not make clear what applicant intends by reciting a member X of a specific binding pair. Applicant is reminded that the claim must stand on

its own merits and that limitations from the specification are not read into the claims.

See also deficiencies found in claim 6 for X and Y members.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-15 and 19-22 are rejected under 35 U.S.C. 102(b) as being anticipated by Frengen (US 5,739,042) in light of Chandler et al (US 5,981,180).

Frogenen discloses a method for detecting an analyte in a sample. Frogenen et al disclose incubating a sample with two independently determinable forms of solid supported binding partner having affinity for the analyte and with a labelled ligand (col 3, lines 55-67, col 8, lines 48-53). Frogenen disclose that the independent forms of solid support can be particles such as microparticles (e.g. col 4, col 9). Frogenen discloses that the labeled ligand (R1) can be associated with a microsphere or particle (solid phase) (col 8, lines 24-38). Frogenen disclose that one of the independent forms of solid support (L1 label) is associated with a specific binding partner (R2) (e.g. col 4, lines 43-51). Frogenen discloses that the second form of solid support (L2 label) is associated with a specific binding partner (R3) for the analyte. Frogenen discloses that the method can be used for qualitative or quantitative measurements (e.g. col 8). Frogenen discloses that the solid support (L1 label) associated with a specific binding partner (R2)

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requires a longer incubation than does the saturation of specific binding partner (R3) (col 5). Frengen discloses that the binding partners on the solid supports can be the same or different (col 9). Frengen discloses that the L1 and L2 supports can both be particles. Thus, Frengen is teaching the same label. Frengen discloses that the method can be a sandwich assay (e.g. col 7). Frengen discloses that the method can include the avidin/biotin system for binding to analyte or for providing for indirect detection of the analyte (col 9).

With respect to "determining an L1-dependent measurement signal at time T1 and an L2-dependent measurement signal at time T2" as instantly recited. Frengen teaches that the independently determinable forms of solid support binding partners bound with the analyte and labeled ligand are determined by flow cytometry in a gated manner (e.g. col 10, lines 20-32). Further, as shown by Chandler et al (US 5,981,180) flow cytometry requires a fluid suspension of particles in a flow down a stream in single file and passed through a examination zone in this manner to detect the individual particles (col 1, lines 55 - col 2 line 17). Thus, it is inherent that the particles of Frengen are being detected at different time intervals.

With respect to the X and Y binding members as instantly recited. Frengen discloses that the method can include the biotin/avidin (X/Y) system for providing binding to the analyte and also for providing for the indirect detection of the analyte (col 9). Further, it is unclear what applicant intends by the X and Y binding members as instantly recited (see 112 2<sup>nd</sup> rejections above). Thus, for the reasons stated above Frengen reads on the instantly recited claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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11. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frengen in view of Burarida et al (Cytometry 37: 21-31, 1999).

See above for the teachings of Frengen.

Frenge differs from the instant invention in failing to teach detection by energy transfer.

Burarida et al teaches that it is known in the art of flow cytometry to incorporate fluorescence resonance energy transfer (FRET) to provide for the determination of  $K_d$  values, which indicate agreement between solution and flow cytometric determinations.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate FRET assays as taught by Burarida et al into the method of Frengen because Burarida et al teaches that this provides for the determination of  $K_d$  values, which indicate agreement between solution and flow cytometric determinations.

12. Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Frengen in view of Ullman et al (Proc. Natl. Acad. Sci USA, Vol 91, pp. 5426-5430, 1994).

See above for the teachings of Frengen.

Frenge differs from the instant invention in failing to teach photosensitizers and chemiluminescent substances.

Ullman et al teach particles comprising photosensitizers and chemiluminescent substances utilized in luminescent oxygen channeling immunoassays (e.g. p. 5426).



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Ullman et al teaches that this provides real-time measurement of particle binding kinetics (p. 5426).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate photosensitizers and chemiluminescent substances such as taught by Ullman et al into the method of Frengen because Ullman et al teaches that this provides for real-time measurement of particle binding kinetics.

### ***Response to Arguments***

13. Applicant's arguments filed 03/04/09 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/

Examiner, Art Unit 1641

/GAILENE R. GABEL/

Primary Examiner, Art Unit 1641

5/25/09